PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Jane P. Bearinger et al	Examiner: Gregory Anderson
Serial No.: 10/781,582	Art Unit: 3773
Filed: 02/17/2004	Attorney Docket No.: IL-11213
TITLE: SYSTEM FOR CLOSURE OF A PHYSICAL ANOMALY	

Honorable Commissioner for Patents
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

APPELLANTS' BRIEF (37 C.F.R. § 1.192)

This brief is submitted in support of Appellants' Notice of Appeal from the October 2, 2008 Office Action. The October 2, 2008 Office Action was a response to Appellants' previous Appeal Brief. The October 2, 2008 Office Action stated "PROSECUTION IS HEREBY REOPNED. New grounds of rejection are set forth ..." Appellants were given the option of (1) filing reply or (2) filing a new appeal.

Appellants elected option (2) filing a new appeal. Appellants' Notice of Appeal was filed November 14, 2008. One copy of the brief is being transmitted per 37 C.F.R. § 41.37.

The October 2, 2008 Office Action stated that claims 1, 4-21, 25, 31, 32, 34, and 35 were rejected; however Appellants believe that claims 7-10 and 18 are cancelled and that claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 are the claims on appeal.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is:

Lawrence Livermore National Security, LLC and the United States of America as represented by the United States Department of Energy (DOE) by virtue of an assignment by the inventor as duly recorded in the Assignment Branch of the U.S. Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

The application as originally filed contained claims 1-35.

The claims on appeal are claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35.

The status of all the claims in the proceeding is:

Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 are rejected.

Claims 2, 3, 7, 8, 9, 10, 18, 22, 23, 24, 26, 27, 28, 29, 30, and 33 are cancelled.

Claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal are reproduced in the Appendix.

IV. STATUS OF AMENDMENTS

There are no amendments subsequent to the December 27, 2007 Final Rejection or the October 2, 2008 Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Appellants' invention provides an apparatus and a method for closure of a physical anomaly that forms a gap in a vascular wall. Appellants' invention provides a closure body made of a shape memory polymer (SMP) foam. The shape memory polymer (SMP) foam has at least one hard segment and one soft segment wherein the hard segment is formed at a temperature above T_{trans} and the soft segment is formed at a temperature below T_{trans}. Appellants' invention is illustrated in FIGS. 1, 2, 3, and 5B reproduced below and described in the portions of the specification quoted below.

> The present invention provides apparatus and methods for closure of a physical anomaly. The closure is provided by a polymer body with an exterior surface. The exterior surface contacts the opening of the anomaly and closes the anomaly. The polymer body has a primary shape for closing the anomaly and a secondary shape that allows it to be positioned in the physical anomaly. (Page 7, Lines 22-26 of Appellants' Specification)

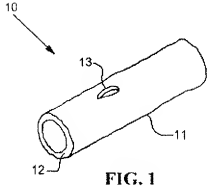


FIG. 1

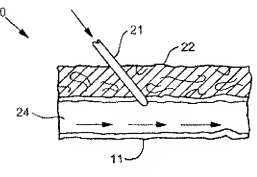


FIG. 2

FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, Lines 20-21 of Appellants' Specification) In order to close such sites, a closure body, in one embodiment a polymeric foam, is advanced to the puncture site in order to seal the site. (Page 9, Lines 5-6 of Appellants' Specification)

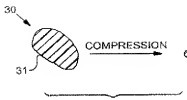


FIG. 3

FIG. 3 is a schematic of a closure body 31 in its expanded state and the closure body 31′ in its compressed state. The closure body 31′ is compressed to a smaller volume before deployment. (Page 10, Lines 15-17 of Appellants' Specification)

SMP foams comprise at least one hard segment and one soft segment. One segment contains a crosslinkable group; linking occurs via charge transfer, chemical or physical segment interactions. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment can return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, Lines 11-16 of Appellants' Specification)

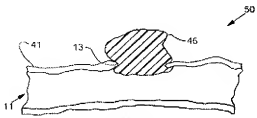


FIG. 5B

Full deployment of the SMP foam closure device is shown in FIG. 5B. The closure body 46 is shown in its expanded state (as opposed to compressed state) to fill the gap in the vessel wall in its entirety. In FIG. 5B, the puncture tract 45 is shown with the delivery catheter removed and with the closure body 46 in its expanded (actuated) state. (Page 13, Lines 24-26 of Appellants' Specification)

Appellants' independent claims 1, 19, and 32 involved in the appeal are "read on" Appellants' specification below. Portions of Appellants' specification are quoted and the paragraph containing the quote is identified by the page and line numbers.

Claim 1	Specification & Drawings
An apparatus for closure of a physical anomaly that forms a gap in a vascular wall, the apparatus comprising:	an apparatus for closure of a physical anomaly having a passage with the passage having an inner surface extending around the passage. (Page 4, lines 11-13) FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, lines 20-21)
a closure body, said closure body made of a shape memory polymer (SMP) foam,	FIG. 3 is a schematic of a closure body 31 (Page 10, line 15) The closure body 31 and 31' is made of a shape memory material. (Page 10, lines 18-19) In another embodiment the polymer is a foam (Page 12, lines 8-8)
said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},	SMP foams comprise at least one hard segment and one soft segment. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment (Page 12, lines 11-15)
said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16)
said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)

Claim 1 (Continued)	Specification & Drawings
said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall, and	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16)
a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2) The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) delivery catheter comprises an actuation method to deploy the closure body 46 and allows it to reach its expanded (actuated) state. (Page 13, lines 8-9)
wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly.	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

Claim 19	Specification & Drawings
A method of closing a physical anomaly that forms a gap in a vascular wall, the method comprising:	The present invention provides apparatus and methods for closure of a physical anomaly. (Page 7, lines 22-23) The embodiment 100, 100′ can be used for the closure of punctures in vascular or non-vascular walls in the body. (Page 8, lines 7-8)
providing a closure body made of a shape memory polymer (SMP) foam,	FIG. 3 is a schematic of a closure body 31 (Page 10, line 15) The closure body 31 and 31' is made of a shape memory material. (Page 10, lines 18-19) In another embodiment the polymer is a foam (Page 12, lines 8-8)
said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},	SMP foams comprise at least one hard segment and one soft segment. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment (Page 12, lines 11-15)
said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16)
compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)

Claim 19 (Continued)	Specification & Drawings
positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall, and	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2) The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) delivery catheter comprises an actuation method to deploy the closure body 46 and allows it to reach its expanded (actuated) state. (Page 13, lines 8-9)
transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly.	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

Claim 32	Specification & Drawings
A system for the closure of a physical anomaly that forms a gap in a vascular wall, the system comprising:	an apparatus for closure of a physical anomaly (Page 4, lines 11-12) FIG. 1 is an isometric schematic of a puncture site 13 through the vessel wall 12 of a vessel 11. (Page 8, lines 20-21)
a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam,	FIG. 3 is a schematic of a closure body 31 (Page 10, line 15) The closure body 31 and 31' is made of a shape memory material. (Page 10, lines 18-19) In another embodiment the polymer is a foam (Page 12, lines 8-8)

Claim 32 (Continued)	Specification & Drawings
said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},	SMP foams comprise at least one hard segment and one soft segment. Objects formed at a temperature above a T_{trans} of the hard segment and cooled to a temperature below the T_{trans} of the soft segment (Page 12, lines 11-15)
said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) cooled to a temperature below the T_{trans} (Page 12, line 14) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall,	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

Claim 32 (Continued)	Specification & Drawings
a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2) The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) delivery catheter comprises an actuation method to deploy the closure body 46 and allows it to reach its expanded (actuated) state. (Page 13, lines 8-9)
said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall,	The closure body 31' is compressed to a smaller volume before deployment. (Page 10, lines 16-17) SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. Page 13, lines 1-2)
means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape; and	a delivery catheter 44 and SMP foam closure body 46 in its compressed state being moved into place to close a vessel 41. (Page 13, lines 1-2)
means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly.	then controllably actuated so that it recovers its primary shape illustrated by the SMP closure body 31. (Page 11, lines 20-23) return to their original shape with heating above the T_{trans} of the soft segment again. (Page 12, lines 15-16) The exterior surface contacts the opening of the anomaly and closes the anomaly. (Page 7, lines 24-25)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The October 2, 2008 Office Action states three (3) grounds of rejection. The three grounds of rejection are summarized as follows:

Grounds of Rejection #1 - Claim 9 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because "The phrase "having a substantially flowing fluid shape" renders the claim indefinite. The rejection is stated in numbered paragraph 3 on pages 2-3 of the October 2, 2008 Office Action.

Grounds of Rejection #2 - Claims 1, 4, 5, 7-12, 14, 16-21, 25, 31, 32, 34, and 35 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans et al U. S. Patent No. 5,549,633 (hereinafter "Evans") in view of Bleys et al U. S. Patent No. 6,034,149 (hereinafter" Bleys"). The rejection is stated in numbered paragraph 5 on pages 3-5 of the October 2, 2008 Office Action. Appellants believe that claims 7-10 and 18 are cancelled; therefore the rejected claims in Grounds of Rejection #2 are claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35.

Grounds of Rejection #3 - Claims 6, 13, and 15 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans in view of Bleys and further in view of Duane et at U. S. Patent No. 5,836,306 (hereinafter" Duane"). The rejection is stated in numbered paragraph 6 on page 5 of the October 2, 2008 Office Action.

VII. ARGUMENT

Argument Relating to Grounds of Rejection #1 - The rejection in Grounds of Rejection #1 is respectfully traversed because claim 9 has been cancelled. Claim 9 was one of the claims that were cancelled by the "Amendment" filed September 21, 2007 which was a response to the Office Action mailed June 27, 2007. Also, note that claim 9 is not listed in CLAIMS APPENDIX (VIII).

Argument Relating to Grounds of Rejection #2 - The rejection in Grounds of Rejection #2 is respectfully traversed because Appellants' claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35 are not obvious over the Evans reference in view of the Bleys reference and Appellants' claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35 are patentable.

The Evans Reference

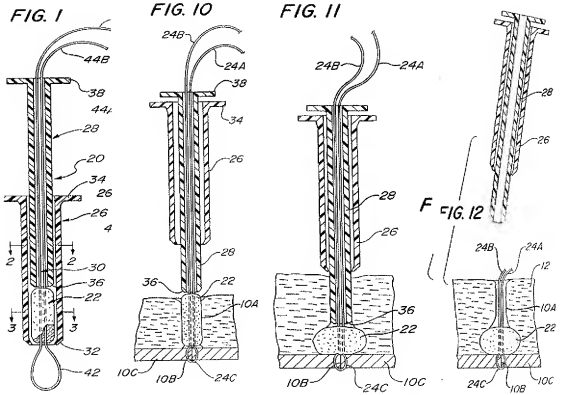
The Evans reference (U.S. Patent No. 5,549,633) is an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). This is substantially different from Appellants' claimed invention which is a "closure of a physical anomaly that forms a gap in a vascular wall." A percutaneous puncture site (puncture tract) is in the tissue outside a vascular wall and is not in the vascular wall itself. Appellants' claimed invention closes a physical anomaly that forms a gap in a vascular wall." The Evans reference is a device for preventing blood seepage in the puncture tract tissue outside the vascular wall. The Evans reference is illustrated in FIGS. 1, 10, 11, and 12 reproduced below and described in the portions of the Evans reference quoted below.

> "Perclose, Inc. of Menlo Park, Calif. has recently disclosed a percutaneous vascular closure device which it designates by the trademark PROSTAR.

The PROSTAR device is arranged to be inserted through a percutaneous puncture into a artery to seal the opening in the arterial wall. To that end the PROSTAR device inserts plural needles having sutures secured thereto through the percutaneous puncture and into the interior of the artery. The needles are then drawn from the interior of the artery through the arterial wall portion surrounding the puncture and out through the puncture tract, where they are grasped to pull the associated sutures out of the puncture tract. The extending portions of the sutures are knotted within the puncture tract and the knots are pushed into the tract by an associated device, designated as the PROSTAR knot pusher, so that the knots are closely adjacent or abutting the exterior of the artery wall. This action ostensibly seals the opening in the artery wall. It is believed that there may be some blood seepage out of the puncture tract when using the PROSTAR system."

"Referring now in greater detail to the various figures of the drawings wherein like reference characters refer to like parts, there is shown at 20 one embodiment of apparatus constructed in accordance with this invention. The apparatus 20 is arranged to be used to apply a self-supporting mass or body of material 22, e.g., collagen like that disclosed in the aforementioned patent, to inhibit the flow of the fluid, e.g., blood, therethrough at or immediately adjacent a percutaneous puncture 10 (FIG. 7) which had been sealed or closed by some means located within the tract of the puncture to prevent the seepage of fluid from the puncture. In the embodiment shown in FIGS. 7-12 the apparatus 20 is shown applying that mass of material 22 into an arterial puncture tract 10A extending through the skin and underlying tissue 12 so that the mass 22 is adjacent the hole or opening 10B in the wall 10C of the artery."

"As will be appreciated from the discussion to follow the apparatus 20 is arranged to place the mass or body 22 either into the percutaneous puncture tract 10A or on the surface of the skin 12 above and contiguous with the puncture 10 to enable the mass to be secured in place in close engagement with the tissue of the puncture tract so that it reduces or prevents the seepage of a fluid from the puncture 10."



"As can be seen in FIG. 1 the apparatus or device 20 basically comprises a tubular housing 26, a tamping member 28, the heretofore identified mass or body 22 of material which is resistant to the passage of a fluid therethrough, and a flexible carrier filament 30. In accordance with a preferred embodiment of this invention the mass or body 22 is composed of collagen foam, since that material enables blood to readily clot therein, thus expediting hemostasis (blood flow stoppage) when the application is used to prevent the seepage of blood from a percutaneous puncture to a blood vessel or some other interior structure in the body of the being. In particular, the mass is preferably a porous sponge of Type 1 collagen marketed by Collatec, Inc. under the trade name HELISTAT. This material is a natural hemostatic material to provide hemostasis and the elimination of any "weeping" or seeping of blood due to incomplete closure of the puncture site by the sutures, as will be described later. Other hemostatic materials, such as cellulose-based, hemostatic materials manufactured and sold by Upjohn Company under the trademark GELFOAM, can also be used for the mass 22. Other blood clotting materials can be used in lieu of collagen. In fact the material of the mass 22 need not even absorb the blood nor promote blood clotting therein, so long as it is resistant to the passage of a fluid therethrough."

"The tubular housing 26 basically comprises a hollow cylinder having an open, slightly inwardly tapered, distal free end 32 and an outwardly flanged proximal free end 34. The housing 26 is arranged to retain the mass 22 therein until it is to be deployed, i.e., expelled or ejected, from the device for disposition at the puncture tract (as will be described later). To that end the housing is shaped so that it can be readily held in the hand of the user to locate it at the desired position for deploying the mass 22. The deployment of the mass from the apparatus is effected by retraction of the housing 26 with respect to the tamper 28 as will be described later."

"The tamper 28 basically comprises a hollow tube having an open distal free end 36 and a flanged proximal free end 38. The outside diameter of the tamper is slightly less than the inside diameter of the housing 26 so that it fits therein and is slidable longitudinally with respect thereto. This enables the housing 34 to be slid or retracted backward with respect to the plunger to expel or eject the mass 22 from the housing. Once the mass 22 has been expelled from the housing the tamper 28 is used to tamp it in place into intimate engagement with tissue contiguous with the puncture tract 10A, i.e., tissue within the tract or the surface of the skin contiguous with the tract, as will be described later."

"The carrier filament 30 basically comprises an elongated flexible member, e.g., a conventional suture, which is folded in two to form a looped distal end 42 and a pair of extending leg portions 44A and 44B. The flexible member 30 extends through the central passageway 40 in the mass 22 so that its looped distal end 42 extends outside (i.e., distally) of the housing's open end 32, and with its leg portions 44A and 44B extending through the hollow interior of the tamper 28 gaining egress out the proximal flared end 38 thereof."

"The apparatus 20 is now ready to deploy the mass 22. To that end the user orients the apparatus so that the distal end 32 of the housing 26 is extended into the puncture tract 10A, like shown in FIG. 9. In this position the mass 22 is disposed immediately over the knot 24D. During the insertion of the distal end of the apparatus into the puncture tract the proximal portions 44A and 44B of the suture are pulled to make them somewhat taut. This facilitates the insertion procedure. Once the apparatus 20 is in position, the housing 26 is slid backward (retracted) with respect to the tamper 28 by squeezing their two flanged portions 34 and 38, respectively together, while holding the tamper 38 stationary. This

action ejects the mass 22 into the puncture tract 10A, whereupon the mass is disposed immediately over the arterial wall, like shown in FIG. 10."

"In order to seat the mass the tamper 28 and housing 26 are then moved as a unit so that the distal end 36 of the tamper 28 engages the mass 22 to deform it as shown in FIG. 11. One or two gentle tamping actions are all that should be necessary to ensure that the mass 22 is in intimate engagement with the sutured opening 10B in the arterial wall. The housing and tamper is then withdrawn as a unit from the puncture tract 10A, as shown in FIG. 12, leaving the mass 22 in place."

"It should be pointed out at this juncture that the frictional engagement between the inner surface of the passageway 40 of the mass 22 and the exterior surface of the extending portions 24A and 24B of the suture 24 should be sufficient to hold the mass 22 in place in the puncture tract 10A to reduce or prevent any blood from seeping out of the puncture tract. Since the mass 22 is preferably formed of a material which promotes clotting upon receipt of blood therein, hemostasis should occur rapidly, thereby quickly preventing any further seepage of blood from the puncture tract."

The Bleys Reference

The Bleys reference is U.S. Patent No. 6,034,149 showing hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons. In general such absorbent articles are relatively voluminous; in particular diapers occupy a lot of space in shops and stores. It would be an advantage to reduce the volume of such absorbent articles without imparting the other properties."

There is No *Prima Facie* Case of Obviousnes

There is no *Prima Facie* case of obviousness that would support the rejection of Appellants' claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35 over the Evans and Bleys references under 35 U.S.C. § 103(a). The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148

USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, "Ascertaining the differences between the prior art and the claims at issue." The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness.

Criterion 1 - The prior art reference (or reference when combined) must teach or suggest all the claim limitations.

Criterion 2 - There must be a reasonable expectation of success with the proposed combination.

Criterion 3 - The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

Criterion 1 - References Do Not Teach All Claim Limitations

The criterion that prior art reference, or references when combined, must teach or suggest all the claim limitations can not be met. With reference to the descriptions of the Evans and Bleys references above, it is clear that the references fail to teach the following limitations of Appellants' claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35:

Claim 1

"An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," or

"wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

Claim 5

"The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall."

Claim 25

"The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger.

Claim 32

"A system for the closure of a physical anomaly that forms a gap in a vascular wall," or

"a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam," or

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall," or

"said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall," or

"means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape;" or

"means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly."

Thus, the combination of the Evans and Bleys references in the Office Action mailed October 2, 2008 does not teach all of Appellants' claim limitations and the combination of the Evans and Bleys references fails to

support a rejection of claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a), and the rejection should be reversed.

Criterion 2 - No Reasonable Expectation of Success

The criterion that there must be a reasonable expectation of success with the proposed combination can not be met. There could be no combination of the Evans reference and the Bleys reference that would provide a reasonable expectation of success or that would show Appellants' invention of amended claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35.

Both the Evans reference and the Bleys reference fail to disclose Appellants' claim 1 limitations: "An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," "wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," "wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

Both the Evans reference and the Bleys reference fail to disclose Appellants' claim 5 limitations: "The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall."

Both the Evans reference and the Bleys reference fail to disclose Appellants' claim 25 limitations: "The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger.

Both the Evans reference and the Bleys reference fail to disclose Appellants' claim 32 limitations: "A system for the closure of a physical anomaly that forms a gap in a vascular wall," "a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam," "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall," "a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure

body into the physical anomaly in the vascular wall," "said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall," "means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape;" "means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly."

Since these elements are missing from both references there could be no combination of the two references that would have reasonable expectation of success of providing Appellant's invention of amended claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35.

The Evans reference requires a carrier filament 30 that basically comprises an elongated flexible member, e.g., a conventional suture, which is folded in two to form a looped distal end 42 and a pair of extending leg portions 44A and 44B. The loop 42 of the carrier filament 30 is adjacent the puncture tract whereupon the extending portions 24A and 24B of the closure 24 are extended or passed through the interior of the loop. Once the extending portions 24A and 24B of the suture are passed through the carrier filament loop 42, the proximally extending portions 44A and 44B of carrier filament are pulled in the proximal direction. This action pulls the extending suture portions 24B and 24C through the passageway 40 of the mass 22, and through the interior of the tamper 28 until those extending portions are located proximally of the flanged end 38. The Bleys reference device does not work with a carrier filament 30 of the Evans reference.

Thus, the combination of the Evans and Bleys references in the Office Action mailed October 2, 2008 fails to support a rejection of claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a), and the rejection should be reversed.

Criterion 3 – No Reasons for Combining the References

The criteriion that the Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007" can not be met. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination. There could be no combination of the Evans reference and the Bleys reference that would show Appellant's invention of amended claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35.

The Evans reference is an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). The Bleys reference shows hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons. There are no reasons for combining these two dissimilar systems. Further, a combination of the Evans reference and the Bleys reference would not show Appellant's invention of amended claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35.

Thus, the combination of the Evans and Bleys references in Grounds of Rejection #2 of the Office Action mailed October 2, 2008 fails to support a rejection of claims 1, 4, 5, 11-12, 14, 16-17, 21, 25, 31, 32, 34, and 35 under 35 U.S.C. § 103(a), and the rejection should be reversed.

Argument Relating to Grounds of Rejection #3 - The rejection in Grounds of Rejection #3 is respectfully traversed because Appellants' claims 6, 13, and 15 are not obvious over the Evans reference in view of the Bleys reference and further in view of the Duane reference. Appellants' claims 6, 13, and 15 are patentable. The Evans reference and the Bleys reference are described above.

The Duane Reference

The Duane reference (U.S. Patent No. 5,836,306) is an exchange accessory for use with a monorail catheter. The Duane reference is illustrated in FIG. reproduced below and described in the portions of the Duane reference quoted below.

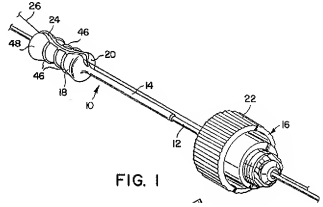


FIG. 1

"Referring now to FIG. 1, a preferred embodiment of the exchange accessory 10 is shown mounted on the proximal end of the shaft of a monorail catheter 12. The exchange accessory 10 includes a sleeve portion 14 that is adapted to be received in a connector 16 (shown broken away). The connector is conventionally mounted on the proximal end of a guide catheter (not shown), external to the patient. The connector 16 may be, for example, a Tuohy-Borst connector or any suitable connector which permits axial positioning of the catheter 12 and permits introduction of a contrast medium or medicament through the guide catheter and into the patient's vascular system. In accordance with one aspect of the invention, the sleeve portion 14 has an internal diameter which is greater than and complementary with the external diameter of the shaft of the particular catheter 12. Thus, the sleeve portion 14 defines a space about the shaft of

the catheter 12 sufficient to allow backbleed of blood therethrough in a controlled manner. To facilitate discussion, the shaft of the catheter 12 is more generally referred to as the catheter 12."

There is No *Prima Facie* Case of Obviousnes

There is no *Prima Facie* case of obviousness that would support the rejection of Appellants' claims 6, 13, and 15 over the Evans, Bleys, and Duane references under 35 U.S.C. § 103(a). The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include, "Ascertaining the differences between the prior art and the claims at issue." The Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness (M.P.E.P. Section 2142). Three basic criteria must be met in order for the Examiner to establish a *prima facie* case of obviousness.

Criterion 1 - The prior art reference (or reference when combined) must teach or suggest all the claim limitations.

Criterion 2 - There must be a reasonable expectation of success with the proposed combination.

Criterion 3 - The Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination.

Criterion 1 - References Do Not Teach All Claim Limitations

The criterion that prior art reference, or references when combined, must teach or suggest all the claim limitations can not be met. With reference to the descriptions of the Evans, Bleys, and Duane references

above, it is clear that the references fail to teach the following limitations of Appellants' claims 6, 13, and 15:

Parent Claim 1

"An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," or

"said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," or

"wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," or

"wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

Claim 6

"The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement."

Thus, the combination of Evans, Bleys, and Duane references in the Office Action mailed October 2, 2008 does not teach all of Appellants' claim limitations and the combination of Evans, Bleys, and Duane references fails to support a rejection of claims 6, 13, and 15 under 35 U.S.C. § 103(a), and the rejection should be reversed.

Criterion 2 - No Reasonable Expectation of Success

The criterion that there must be a reasonable expectation of success with the proposed combination can not be met. There could be no combination of Evans, Bleys, and Duane references that would provide a reasonable expectation of success or that would show Appellants' invention of amended claims 6, 13, and 15.

The Evans, Bleys, and Duane references fail to disclose Appellants' parent claim 1 limitations: "An apparatus for closure of a physical anomaly that forms a gap in a vascular wall," "said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall," "said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall," "wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall," "wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers

its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly."

The Evans, Bleys, and Duane references fail to disclose Appellants' claim 6 limitations: "The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement."

Since these elements are missing from all three references there could be no combination of the three references that would have reasonable expectation of success of providing Appellant's invention of amended claims 6, 13, and 15.

Thus, the combination of Evans, Bleys, and Duane references in the Office Action mailed October 2, 2008 fails to support a rejection of claims 6, 13, and 15 under 35 U.S.C. § 103(a), and the rejection should be reversed.

Criterion 3 – No Reasons for Combining the References

The criteriion that the Examiner must follow the "Examination Guidelines for Determining Obviousness in Light of the Supreme Court's KSR v. Teleflex Decision" published October 10, 2007" can not be met. These guidelines include the requirement that the Examiner provide reasons for combining the references to produce the proposed combination. There could be no combination of Evans, Bleys, and Duane references that would show Appellant's invention of amended claims 6, 13, and 15.

The Evans reference is an apparatus for preventing blood seepage at a percutaneous puncture site (puncture tract). The Bleys reference shows hydrophilic flexible polyurethane foams that are described as being "used to prepare absorbent articles like diapers, sponges, wound dressings and tampons. The Duane reference is an exchange accessory for use with a

monorail catheter. There are no reasons for combining these three dissimilar systems. Further, a combination of the Evans, Bleys, and Duane references would not show Appellant's invention of amended claims 6, 13, and 15.

Thus, the combination of Evans, Bleys, and Duane references in Grounds of Rejection #3 of the Office Action mailed October 2, 2008 fails to support a rejection of claims 6, 13, and 15 under 35 U.S.C. § 103(a), and the rejection should be reversed.

SUMMARY

Appellants have shown that Grounds of Rejection #1, 2, and #3 contain reversible error. It is respectfully requested that the rejections be reversed and claims 1, 4-6, 11-17, 19-21, 25, 31, 32, 34, and 35 on appeal be allowed.

Respectfully submitted,

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VIII. CLAIMS APPENDIX

1. An apparatus for closure of a physical anomaly that forms a gap in a vascular wall, the apparatus comprising:

a closure body, said closure body made of a shape memory polymer (SMP) foam,

said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},

said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall, and

a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape in said delivery device by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,

wherein said shape memory polymer (SMP) foam of said closure body in said reduced secondary stable shape is configured for positioning said closure body within the physical anomaly in the vascular wall, and

wherein said shape memory polymer (SMP) foam is controllably actuated by being heated to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall with said primary shape configured to close said anomaly.

4. The apparatus of claim 1 including actuator means for controllably actuating said shape memory polymer (SMP) foam having at least one hard segment wherein said hard segment is formed at a temperature above T_{trans} by changing said temperature above T_{trans} .

5. The apparatus of claim 1 wherein said delivery device includes a tube and a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall.

6. The apparatus of claim 1 wherein said delivery device includes a tube, a plunger in said tube that deploys said closure body into the physical anomaly in the vascular wall, and a restraint tube for backbleed measurement.

11. The apparatus of claim 1 wherein said delivery device is a delivery catheter.

12. The apparatus of claim 1 wherein said delivery device includes a plunger actuator.

13. The apparatus of claim 1 wherein said delivery device includes a backbleed tube.

14. The apparatus of claim 1 wherein said delivery device includes a plunger actuator and a delivery catheter.

15. The apparatus of claim 1 wherein said delivery device includes a delivery catheter, a plunger actuator, and a restraint tube.

16. The apparatus of claim 1 wherein the physical anomaly is an arteriotomy puncture site.

17. The apparatus of claim 1 including actuator means for controllably actuating said shape memory polymer (SMP) foam, said actuator means configured to transition said closure body from said reduced secondary shape to said primary shape by changing said temperature above T_{trans} by heating.

19. A method of closing a physical anomaly that forms a gap in a vascular wall, the method comprising:

providing a closure body made of a shape memory polymer (SMP) foam,

said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},

said shape memory polymer (SMP) foam capable of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

compressing said shape memory polymer (SMP) foam into a reduced secondary stable shape by cooling said shape memory polymer (SMP) foam to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall when said closure

body is in said reduced secondary stable shape with a volume smaller than the gap in the vascular wall, and

transitioning said closure body made of a shape memory polymer (SMP) foam to said primary shape within the physical anomaly in the vascular wall by heating said shape memory polymer (SMP) foam and changing said temperature above T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall thereby closing said physical anomaly.

20. The method of claim 19 wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system that uses light, coherent light, or heat.

21. The method of claim 20, wherein said step of transitioning the closure body comprises transitioning the closure body with an actuator system chosen from the group consisting of external sheaths, removable sheaths, constraint sheaths, light, coherent light, heat, externally applied energy, plungers, RF, induction, stress, and combinations thereof.

25. The method of claim 19 wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall with a plunger.

31. The method of claim 19 wherein the physical anomaly is chosen from the group consisting of arteriotomy puncture sites, septal defects, patent ductus, and combinations thereof and wherein said step of positioning said closure body made of said shape memory polymer (SMP) foam in the physical anomaly in the vascular wall further comprises positioning said closure body made of said shape memory polymer (SMP) foam in said

arteriotomy puncture sites, septal defects, patent ductus, or combinations thereof.

32. A system for the closure of a physical anomaly that forms a gap in a vascular wall, the system comprising:

a closure body for closing the anomaly, said closure body made of a shape memory polymer (SMP) foam,

said shape memory polymer (SMP) foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans},

said shape memory polymer (SMP) foam having the ability of being formed into a primary shape at temperature above T_{trans} with a volume larger than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being compressed into a reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall,

said shape memory polymer (SMP) foam having the ability of being controllably actuated so that it recovers its primary shape with a volume larger than the gap in the vascular wall,

a delivery device adapted to received said closure body made of a shape memory polymer (SMP) foam with said shape memory polymer (SMP) foam being compressed into said reduced secondary stable shape by being cooled to a temperature below the T_{trans} with a volume smaller than the gap in the vascular wall, said delivery device adapted to deploy said closure body into the physical anomaly in the vascular wall,

said shape memory polymer (SMP) foam reduced secondary stable shape configured for positioning said closure body in the physical anomaly in the vascular wall,

means for positioning said closure body in the physical anomaly in the vascular wall when said closure body is in said reduced secondary stable shape; and

means for transitioning said closure body to said primary shape by heating said shape memory polymer (SMP) foam to a temperature above the T_{trans} so that it recovers its primary shape with a volume larger than the gap in the vascular wall for closing said anomaly.

34. The system for the closure of a physical anomaly of claim 32 wherein said shape memory polymer (SMP) foam of said closure body with a secondary shape for being positioned in the physical anomaly and a larger primary shape for closing said anomaly, said shape memory polymer foam having at least one hard segment and one soft segment wherein said hard segment is formed at a temperature above T_{trans} and said soft segment is formed at a temperature below T_{trans} and wherein said means for transitioning said closure body changes said temperature above T_{trans} by heating.

35. The system of claim 32 wherein said means for positioning said closure body in the physical anomaly in the vascular wall is a delivery catheter.

IX. EVIDENCE APPENDIX

There are no entries in the Evidence Appendix.

X. RELATED PROCEEDINGS APPENDIX

There are no entries in the Related Proceedings Appendix.